

DOCKET NO.: MERK-0004
Application No.: 09/632,422
Office Action Dated: July 7, 2003

**PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116**

REMARKS/ARGUMENTS

The foregoing Amendment after Final and the following Remarks are submitted in response to the Final Office Action mailed July 7, 2003 (Paper No. 9) in connection with the above-identified application and are being filed within the first month after the three-month shortened statutory period set for a response by the Final Office Action.

Claims 1, 2, and 4-58 remain pending in the present application. Claims 10-58 have been withdrawn from further consideration as being directed to a non-elected invention. Claim 1 has been amended to more particularly point out and distinctly claim the subject matter of the present invention in a manner suggested by the Examiner. Applicant respectfully submits that no new matter has been added to the application by the Amendment after Final.

The Examiner has again rejected claims 1, 2, and 4-9 under 35 U.S.C. §103(a) as being obvious over the S-PLUS statistical data analysis software as produced and/or marketed by MATHSOFT, Inc. of Cambridge, Massachusetts. Applicant again respectfully traverses the §103(a) rejection insofar as it may be applied to the claims as amended.

Independent claim 1 as amended recites a method of evaluating raw assay data that is arranged in a three dimensional array, where the raw assay data is derived from an assay and the assay is subject to systematic and positional effects. In the method, a high throughput screening assay is performed to identify a biologically active agent in a collection of test agents, where the raw assay data is generated from the assay. The raw assay data is compensated for the systematic

and positional effects. Thereafter, the compensated data is scored and formatted according to a determined format, and the biologically active agent is identified by identifying a test agent that generates a data point which statistically deviates from other data points in the formatted scored data.

As was previously pointed out, the specification of the present application discloses that the S-PLUS software is statistical data analysis software which may be employed to perform statistical analyses and manipulations on data. Thus, the S-PLUS software provides statistical functions that may be employed in connection with the present invention. However, and significantly, the S-PLUS software does not disclose that any particular type of data be employed therewith, and in particular does not disclose or suggest that it be employed to compensate raw assay data for systematic and positional effects, as is required by claim 1.

Moreover, the S-PLUS software is not at all concerned with generating the raw assay data from a high throughput screening assay to identify a biologically active agent in a collection of test agents, as is required by claim 1, nor is such S-PLUS software employable to generate such raw assay data. *In fact, and as the Examiner has suggested, claim 1 has been amended to positively recite the performance of a high throughput screening assay to generate the raw assay data, which again the S-PLUS software cannot do.*

To reiterate, the S-PLUS software is only employed to compensate the raw assay data, and such S-PLUS software is not otherwise used in connection with the present invention as recited in claim 1. Thus, such S-PLUS software does not and cannot score and format the compensated raw assay data, as is required by claim 1,

nor can the S-PLUS software identify a biologically active agent by identifying a test agent that generates a data point which statistically deviates from other data points in the formatted scored data, as is required by claim 1. Instead, and typically although not necessarily, a human being or another computer process is required to perform such scoring, formatting, and identifying.

Accordingly, Applicant respectfully submits that the S-PLUS statistical data analysis software cannot be applied to make obvious claim 1 or any claims depending therefrom including claims 2 and 4-9. As a result, Applicant respectfully requests reconsideration and withdrawal of the §103(a) rejection.

The Examiner has also rejected claims 1, 2, and 4-9 under 35 U.S.C. §101 as being directed to non-statutory subject matter. Applicant respectfully traverses the §101 rejection insofar as it may be applied to the claims as amended.

According to the Examiner, the claims of the present application are directed to the manipulation of data. Moreover, the Examiner notes that although data is generated, such generating is with respect to data and not specifically with respect to the running of an assay. Accordingly, and again as suggested by the Examiner, claim 1 has been amended to positively recite the performance of a high throughput screening assay to generate the raw assay data. As should be appreciated, such performing of an assay is not merely a manipulation of data but requires actually running an assay.

Accordingly, Applicant respectfully submits that claim 1 and all claims depending therefrom including claims 2 and 4-9 are now statutory inasmuch as the claims are not merely reciting the manipulation of data but instead are now positively

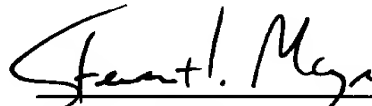
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reciting the performance of the assay as a physical action that must be taken. As a result, Applicant respectfully requests reconsideration and withdrawal of the §101 rejection.

In view of the foregoing Amendment and Remarks, Applicant respectfully submits that the present application including claims 1, 2, and 4-9 is in condition for allowance, and such action is respectfully requested.

Date: October 24, 2003

A handwritten signature in black ink, appearing to read "Steven H. Meyer", written over a horizontal line.

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